EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60132228 0001

Report No.: 15061547 007

Manufacturer:
Innovative Material and
Devices, Inc.
Building #5, No. 615, Fengdeng
Rd., Jia Ding District
201801 Shanghai
China

Products:
Medical Devices

(see attachment for products included)

Replace Approval, Registration No.: DD 60087243 0001

Expiry Date: 2023-08-27

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Notified Body

Effective Date: 2018-08-28

Date: 2018-08-28

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60132228 0001
Report No.: 15061547 007

Manufacturer: Innovative Material and Devices, Inc.
Building #5, No. 615, Fengdeng Rd., Jia Ding District
201801 Shanghai
China

Products:

- Orthodontic Archwires
- Root Canal Instruments
- Metal Brackets
- Bands
- Buccal Tubes/Lingual Attachments
- Ceramic Brackets
- Orthodontic Elastics

Notified Body

Date: 2018-08-28

X. Ren

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Business Stream Products
Certification Department

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TÜV Rheinland LGA Products GmbH • 51105 Köln

Innovative Material and Devices, Inc.
Building 2, No.345 Yanxin Rd.,
Huishan District, Wuxi, 214174 Jiangsu,
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date January 14, 2025

Application for: QMS
Certificate No. : DD 60132228 0001
Requirement : MDD 93/42/EEC Annex V
Confirmation letter ID : DOC_2025-01-10_ DD 60132228 0001
Report no. : 326059512-200

Dear Madame or Sir,

Update of information to Certificate no. DD 60132228 0001, issued on 28.08.2018

The change notification received on 16.10.2024 related to the information stipulated on the above mentioned certificate was assessed and information confirmed.
We confirm that the change notification is not considered a significant change in design or intended purpose under Regulation (EU) 2017/745 on medical devices (MDR), Article 120(3).

With this document we would like to confirm the following updated information to the afore mentioned certificate

Revised Manufacturer address

Old Manufacturer address:	Building #5, No. 615, Fengdeng Rd., Jia Ding District, 201801 Shanghai
New Manufacturer address:	Building 2, No.345 Yanxin Rd., Huishan District, Wuxi, 214174 Jiangsu, P.R. China

Best regards,

Jason Pan
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
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Germany

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Business Stream Products
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Jiading District,
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P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date January 17, 2024

Notified Body Confirmation Letter
Reference. : 244563049

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Innovative Material and Devices, Inc.
Building#5, NO.615 Fengdeng Rd., Jiading District,
201801 Shanghai,
P.R. China
SRN Number: CN-MF-000002280

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

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The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Fuxiu Sheng
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Orthodontic Archwires model: Niti Wires Basic UDI-DI: 695706700003-0373FD	Class IIa	NA	Certificate # DD 60132228 0001; NB# 0197
Orthodontic Archwires model: Stainless Steel Wires Basic UDI-DI: 695706704677-4791UQ	Class IIa	NA	Certificate # DD 60132228 0001; NB# 0197
Orthodontic Archwires model: Beta Ti Wires Basic UDI-DI: 695706701462-1631MF	Class IIa	NA	Certificate # DD 60132228 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	**MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)**	**If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device**	**MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification**
Orthodontic Archwires model: Cu-Ni Wires Basic UDI-DI: 693694923198-3320ZM	Class IIa	NA	Certificate # DD 60132228 0001; NB# 0197
Metal Brackets model: Self-ligating brackets Basic UDI-DI: 69570670 6518-6669TA	Class IIa	Metal Brackets Type: MIM; Model: Auta series, Copolla series, Ophor series, ProMIM series and ActMIM series	Certificate # DD 60132228 0001; NB# 0197
Metal Brackets model: None self-ligating brackets Basic UDI-DI: 695706706001-7000K4	Class IIa	Metal Brackets Type: MIM; Model: Auta series, Copolla series, Ophor series, ProMIM series and ActMIM series	Certificate # DD 60132228 0001; NB# 0197
Orthodontic bands and attachments model: Smooth inner surface Basic UDI-DI: 69369492 1786-2208 2F	Class IIa	Bands (Various sizes; Smooth inner surface bands)	Certificate # DD 60132228 0001; NB# 0197
Orthodontic bands and attachments model: Rough inner surface Basic UDI-DI: 693694922001-3197RG	Class IIa	Bands (Various sizes; Rough inner surface bands)	Certificate # DD 60132228 0001; NB# 0197
Buccal Tubes model: Weldable Basic UDI-DI: 693694926636-74003P	Class IIa	Buccal Tubes (Type: Non-MIM, MIM; Model: weldable edgewise tube, weldable MBT/Roth tubes)	Certificate # DD 60132228 0001; NB# 0197
Buccal Tubes model: Bondable Basic UDI-DI: 695706708001-8930NF	Class IIa	Buccal Tubes (Type: Non-MIM, MIM;	Certificate # DD 60132228 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
		Model: bondable edgewise tubes, bondable MBT/Roth tubes)	
Root Canal instruments model: Standard instrument Basic UDI-DI: 693694921600-6668V5	Class IIa	Root Canal instruments model: Rotary root canal instruments	Certificate # DD 60132228 0001; NB# 0197
Root Canal instruments model：Taper instrument Basic UDI-DI: 693694926669-99748M	Class IIa	Root Canal instruments model: Rotary root canal instruments	Certificate # DD 60132228 0001; NB# 0197
Root Canal instruments model: non-single taper instrument Basic UDI-DI: 695706709501-9614RX	Class IIa	Root Canal instruments model: Rotary root canal instruments	Certificate # DD 60132228 0001; NB# 0197
Orthodontic Elastics model: Ligature tie Basic UDI-DI: 693694923501-3961VR	Class IIa	NA	Certificate # DD 60132228 0001; NB# 0197
Orthodontic Elastics model: Separator Basic UDI-DI: 693694923959-396165	Class IIa	NA	Certificate # DD 60132228 0001; NB# 0197
Orthodontic Elastics model: Power Chain Basic UDI-DI: 693694923666-39173K	Class IIa	NA	Certificate # DD 60132228 0001; NB# 0197
Orthodontic Elastics model: O-ring Basic UDI-DI: 693694923919-39584C	Class IIa	NA	Certificate # DD 60132228 0001; NB# 0197
Ceramic Brackets model: Edgewise	Class IIa	NA	Certificate # DD 60132228 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Basic UDI-DI: 695706709001-9100MU			
Ceramic Brackets model: ROTH Basic UDI-DI: 695706709009-9100R4	Class IIa	NA	Certificate # DD 60132228 0001; NB# 0197
Ceramic Brackets model: MBT Basic UDI-DI: 695706709068-9093UR	Class IIa	NA	Certificate # DD 60132228 0001; NB# 0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	**N/A**	**N/A**	**N/A**

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/01/17	244563049	Initial issue